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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,411

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Scott C. Anderson

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SJM/AFD-WILEY

Legal Department

One St. Jude Medical Drive

St. Paul, MN 55117-9913

EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,411	<b>Applicant(s)</b> ANDERSON ET AL.	
	<b>Examiner</b> david shay	<b>Art Unit</b> 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on September 8, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 50-54, 83-97 and 99-108 is/are pending in the application.
- 4a) Of the above claim(s) 50-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-97 and 99-108 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :May 11, 2009 and September 8, 2009.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant argues that since the device of Choy “vaporizes the obstruction, *which is constantly removed by suction*” and thus cannot teach an ablating device adapted to temporarily mechanically couple to a tissue surface. The examiner must respectfully disagree, however, since, even assuming that, as applicant appears to be arguing, the tissue which the catheter adheres to is vaporized, and thus no longer available for attaching to, the catheter would still *temporarily* be attached until that portion of the obstruction was ablated. However, as can readily be seen from Figure 2 of Choy et al, the tunnel through the obstruction does not remove the portions of the obstruction that the catheter is contacting. This only makes sense, since even if the radiation were sent out in a wide enough pattern to head towards this portion of the obstruction, the energy would be intercepted by the portion of the catheter forming the outer lip before it had a chance to strike and ablate that portion of the obstruction. Thus this argument is not convincing.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Firstly, applicant argues that Choy does not teach a “suction well”, but simply teaches “a conduit 10 having a fiberoptic bundle 16 at the distal end of the conduit 10 and an annular space between the walls of the conduit 10 and the fiberoptic bundle” citing column 3, lines 46-58 of Choy. Then applicant observes “the examiner does not identify any structure in Choy that allegedly constitutes a suction well” (see the instant response, page 9, second full sentence). The examiner apologizes for any confusion engendered by his explanation. However the structure constituting the “suction well” constitutes the annular space separating the structures constituting the inner and outer lips thereof, set forth in the explanation of the Choy reference, similar to the location of the suction well in applicant’s device. Continuing applicant asserts that the “light source conducting fibers 24 of Choy do not surround a perimeter of the laser energy conducting fibers 26. The examiner must respectfully disagree. It is well understood that claim terms are to be given their broadest reasonable interpretation, in light of the specification. It is further respectfully noted that the claim does not require that the inner lip completely surround the ablating element, nor that the inner lip surround the ablating element at a constant distance, ergo an inner lip that merely partially surrounds the ablating element, as the viewing fibers of Choy do the ablating fibers thereof, also reads upon the broadest reasonable interpretation of the term “surrounding”. Thus this argument is not convincing.

With regard to the teachings of Edwards et al (’798), applicant argues that the suction ports are close to but do not surround the ablating element. The examiner can find no support for such an assertion in the Edwards et al (’798) reference. Edwards et al (’798) makes no statement to the effect that the suction ports do not surround the ablating elements thereof, nor can any lack of surrounding, either full or partial, be inferred from the disclosure that the suction

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ports are “close to” the ablating elements. Thus it is unclear to the examiner the manner in which applicant’s very broad claim language reads over the applied art. Separate and apart from the foregoing, it is further noted that the device of Edwards et al (’798) also includes balloons (see Figures 67 and 70), which could just as easily be deemed the “outer lip” of the suction well, with the wall constituting the orifice through which an electrode protrudes constituting an “inner lip”. Thus even if applicant were to successfully argue that the recesses, or wells containing the ablating electrodes and suction ports of Edwards et al (’798) (see, e.g. column 61, lines 52-64) are not “suction wells”, which the examiner emphatically notes has in no way been done, the examiner submits that the structure between the outer lips formed by the balloons could still be so construed and thus read on the claims.

Continuing, applicant argues that claim 104 distinguishes over Edwards et al (’798) as applied by the examiner. In addition to the interpretations of Edwards et al (’798) explicated above, the examiner notes that two opposing walls of the recesses or wells of Edwards et al (’798) are coplanar, as can be clearly seen in the illustration of Figure 71. The portion of the recess defining the edge thereof which is closest to the electrode port, 304 being considered inner walls, and the portion of the recess defining the edge thereof nearest suction port 306 being considered the outer wall, these are both coplanar.

The obviousness-type double patenting rejection based on Flom is withdrawn in view of applicant’s arguments.

The remaining obviousness-type and provisional obviousness-type double patenting rejection has been maintained.

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Claims 83, 89, 90, 94, and 97 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Choy.

See Figure 1, wherein the distal tip of the device is the outer lip, the laser fiber is the ablating element, the ring of illumination fibers (see Figure 4) constitutes an inner lip, which are substantially coplanar with the outer lip and the annular volume surrounding the fiber constitutes a fluid chamber, and the portion of the catheter proximal of the fiber is the suction lumen, the suction port being that portion of the catheter coupled to the suction source.

Claims 83-89, 94, 96, 97, 99-101 and 104 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Edwards et al ('798).

Edwards et al ('798) teach a device as claimed (see Figures 68-71) wherein the insulation of the electrode constitutes the inner lip of the suction well.

Claims 84-88, 91-93, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choy. Choy teaches a device as claimed except the multiple wells, the sensors and the particular ratio of the suction lumen cross section to the vacuum port cross section. It would have been obvious to the artisan of ordinary skill to provide multiple ports for multiplied effect, such as operating on multiple cardiac vessels simultaneously, and to provide a pressure, flow rate, or electrical sensor since these are equivalent to the reservoir 30 of Choy, as they would serve to distinguish when the thrombus is breached and provide no unexpected result, and to provide the particular ratio of the port cross section to the lumen cross section since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result, thus producing a device such as claimed.

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Claims 90-93, 95, 102, 103, and 105-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al ('798). Edwards et al ('798) teaches a device as claimed except the particular vacuum sensors and the particular ratio of the suction lumen cross section to the vacuum port cross section and the ablating element being recessed with respect to the coplanar inner and outer walls. It would have been obvious to the artisan of ordinary skill to provide and to provide a flow rate or electrical, sensor since these are equivalent to the reservoir vacuum sensor of Edwards et al ('798), since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result, and would serve to distinguish when the device becomes dislodged, to provide the particular ratio of the port cross section to the lumen cross section since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result, and to provide coplanar walls, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would allow cooling fluid to be administered top the surface tissue where the electrode is inserted , thereby preventing damage thereto, thus producing a device such as claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



Claims 83-97 and 99-108 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,161,543.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent application claims. Here, the patent application claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 83-97 and 99-108 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of U.S. Patent No. 6,237,605.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent application claims. Here, the patent application claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

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Claims 83-97 and 99-108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent Application No. 11/882,072. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 83-97 and 99-108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent Application No. 11/646,524. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant

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application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 83-97 and 99-108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent Application No. 11/878,375. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed May 11, 2009 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769